



F. & A. PHARMA-Handels-GmbH
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CHEMICALS SBU

Works :

294, G.I.D.C., Estate,
Ankleshwar - 393 002.
Gujarat, India.

01/07/2022 METAPHARMACEUTICAL

N DE LOTE:

0060922

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Name of Finished Drug substance: Fluoxetine Hydrochloride Ph.Eur/BP+IH.

Manufactured By.	Cadila Pharmaceuticals Limited, Ankleshwar		
Batch No.	22FH152	A.R. No.	22FP0776
Manufacturing Date	JUNE 2022	Qty. Mfgd.	156.21 Kg.
Expiry Date	MAY 2027	Sample Qty.	125.85 gm
Specification No	FPS/239	CEP No	R1-CEP 2004-207-Rev 06
Storage condition	Store in a tightly closed container at room temperature. (Not more than 25°C, excursion allowed 15°C to 30°C).		

Certificate of Analysis

Test	Requirements	Results
Characters:		
A. Description	A. White or almost white crystalline powder.	White crystalline powder.
B. Solubility	B. Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.	Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.
Identification		
A. By IR	A. The infrared absorption spectrum obtained from the sample should be concordant with the spectrum obtained from Fluoxetine Hydrochloride for ID and assay CRS/ Fluoxetine Hydrochloride working standard.	The infrared absorption spectrum obtained from the sample is concordant with the spectrum obtained from Fluoxetine Hydrochloride working standard.
B. Test for chloride	B. Should be responds the chlorides	Complies
Appearance of solution	Solution should be clear and colorless	Solution clear and colorless
pH	Between 4.5 and 6.5	6.34
Optical rotation	Between - 0.05° and + 0.05°	+0.00°
Water content (By KF)	Not more than 0.50 % w/w	0.06 % w/w
Sulfated ash	Not more than 0.10 % w/w	0.05 % w/w
Related substances (By HPLC)		
Impurity A	Not more than 0.15 %	Below Quantification limit
Impurity B	Not more than 0.10 %	Below Detection limit
Dimethyl amine impurity	Not more than 0.10 %	Not Detected
Unspecified impurity	Not more than 0.10 %	0.01 %
Total impurities	Not more than 0.30 %	0.01 %
Assay (By HPLC)	Not less than 98.0 % w/w and not more than 102.0 % w/w of C ₁₇ H ₁₈ F ₃ NO.HCl, calculated on the anhydrous basis	100.5 % w/w
Residual solvents (By GC)		
Benzene	Not more than 1 ppm	Not Detected
Ethyl acetate	Not more than 5000 ppm	Not Detected
Toluene	Not more than 100 ppm	Not Detected

Additional Test:

Particle size (By Malvern analyzer)	90 % less than 50 µ	90 % particles are 19.0 µ
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Remarks: The material complies with respect to the above specifications.

Statement of Compliance: We, hereby confirm that this batch is manufactured in accordance with current Good Manufacturing Practices.

	Prepared By	Checked By	Approved By
Name	Ankit Pokar	Lalit Kapadia	Manoj Gujar
Designation	Sr.Officer-QA	Dy.Manager-QA	Sr.Manager-QA
Signature			
Date	09.07.22	09.07.22	09.07.22

F/QA007/14/13.04.18

Registered Office :
"Cadila Corporate Campus,"
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CIN : U24231GJ1991PLC015132

The Care Continues ...



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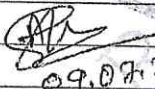


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Limit of Detection (LOD) and Limit of Quantification (LOQ) table:

Name of compound	Limit of Detection (LOD) %	Limit of Quantification (LOQ) %
Impurity A	0.002	0.004
Impurity B	0.002	0.005
Fluoxetine	0.004	0.010
Dimethyl amine impurity	0.004	0.009

Limit of Detection (LOD) and Limit of Quantification (LOQ) table:

Name of compound	Limit of Detection (LOD) ppm	Limit of Quantification (LOQ) ppm
Ethyl Acetate	0.495	1.500
Benzene	0.050	0.150
Toluene	0.165	0.500

	Prepared By	Checked By	Approved By
Name	Ankit Pokar	Lalit Kapadia	Manoj Gujar
Designation	Sr.Officer-QA	Dy.Manager-QA	Sr.Manager-QA
Signature			
Date	09.07.22	09.07.22	09.07.22

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